

PATENT Attorney Docket No. EXT-026 (2457/23)

#### IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

APPLICANT(S):

Lapidus et al.

SERIAL NO.:

09/545,162

**GROUP NO.:** 

1634

FILING DATE:

April 7, 2000

**EXAMINER:** 

Einsmann, J.

TITLE:

Methods For Detecting Nucleic Acids Indicative of Cancer

### CERTIFICATE OF FIRST CLASS MAILING UNDER 37 C.F.R. 1.8

I hereby certify that this correspondence, and any document(s) referred to as enclosed herein, is/are being deposited with the United States Postal Service as first class mail, postage prepaid, in an envelope addressed to the Commissioner for Patents, P.O. Box 1450, Arlington, VA 22202-1450 on this \_5 th day of June 2003.

Thomas F. Hellenthal

Commissioner for Patents P.O. Box 1450 Arlington, VA 22202-1450

Sir:

#### Submitted herewith is/are:

- 1. Transmittal Form (1 page);
- 2. Information Disclosure Statement (2 pages);
- 3. Form PTO 1449 (22 pages);
- 4. Copies of references A1-A117, B1-B111, C1-C177 (A1-A117 and B1-B27 in Box 1; B28-B111 in Box 2; C1-C177 in Box 3);
- 5. Return Receipt Postcard.

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Application Serial Number	09/545,162
Filing Date	April 7, 2000
First Named Inventor	Lapidus
Group Art Unit	1634
Examiner Name	Einsmann, J.
Attorney Docket No.	EXT-026
Patent No.	Not applicable
Issue Date	Not applicable

A TRADEMAN			First Named	Inventor	1	Lapidus
	TRANSMITTA	T	Group Art U	nit	1	634
			Examiner Na	ame	1	Einsmann, J.
	FORM		Attorney Docket No.		1	EXT-026
			Patent No.		1	Not applicable
			Issue Date		1	Not applicable
		ENC	LOSURES (ci	heck all that apply)		
☐ Fe	e Transmittal Form		Copy of Notice	to File Missing		Notice of Appeal to Board
	☐ Check Attached☐ Copy of Fee Transmittal Form		Parts of Applic			of Patent Appeals and Interferences  Appeal Brief (in triplicate)
	Amendment/Response with Declaration attachment Preliminary	]	Request For Co Examination (I Transmittal			Status Inquiry
	After Final				$\boxtimes$	Return Receipt Postcard
	☐ Affidavits/declaration(s) ☐ Letter to Official Draftsperson including Drawings		Power of Attor (Revocation of		$\boxtimes$	Certificate of First Class Mailing under 37 C.F.R. 1.8
	[Total Sheets]		Terminal Discl	aimer		Certificate of Facsimile Transmission under 37 C.F.R. 1.8
	Petition for Extension of Time			aration and Power Utility or Design tion		Additional Enclosure(s) (please identify below)
	Information Disclosure Statement	<u> </u>	Small Entity St	tatement		
	<ul> <li>✓ Form PTO-1449</li> <li>✓ Copies of IDS</li> <li>Citations A1-A117,</li> <li>B1-B111, C1-C177</li> </ul>		CD(s) for large program	table or computer		
	Certified Copy of Priority		Amendment A	fter Allowance		
_	Document(s)		Request for Ce	rtificate of		
	Copy of Sequence Listing submission  Paper Copy/CD Copy of Computer Readable Copy		Correction  Certificate duplicate)	of Correction (in		
	☐ Statement verifying identity of above					
CORR	ESPONDENCE ADDRESS			SIGNATURE BLO	OCK	
Direct a	Testa, Hur High Stree 125 High Boston, M Tel. No.: (	Street	000	Date: June 5, 200 Reg. No. 51,752 Tel. No.: (617) 310- Fax No.: (617) 248-	842.	

Boston, MA 02110



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Einsmann, J.

TITLE:

Methods For Detecting Nucleic Acids Indicative of Cancer

Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450

### INFORMATION DISCLOSURE STATEMENT

Sir:

In accordance with the provisions of 37 C.F.R. 1.97 and 1.98, Applicants hereby make of record the patents and publications listed on the accompanying Form PTO-1449, and other information contained herein, for consideration by the Examiner in connection with the examination of the above-identified patent application. Copies of the patents and publications are enclosed.

In addition, Applicants notify the Examiner of the following U.S. patent applications: U.S. Serial No. 09/514,865, filed February 28, 2000; U.S. Serial No. 09/455,950, filed December 7, 1999; U.S. Serial No. 10/149,464, filed June 7, 2002; and U.S. Serial No. 09/724,274, filed November 28, 2000. Furthermore, Applicants notify the Examiner that U.S. Patent No. 6,084,091 (A111) is the English language counterpart of Foreign Patent Document Nos. 195 30 132C2 (B47), 195 30 132A1 (B110) and WO 97/07239 (B58); U.S. Patent No. 6,150,100 (A109) is the English language counterpart of Foreign Patent Document No. 197 12 332A1 (B48); U.S. Patent No. 6,448,002B1(A110) is the English language counterpart of Foreign Patent Document No. WO 98/08971 (B61); and an English language abstract for Foreign Patent Document No. 197 36 691A1 (B49) is contained in related Foreign Patent Document No. WO 99/10528 (B111).

#### REMARKS

In accordance with the provisions of 37 C.F.R. 1.97, this statement is being filed (CHECK ONE):

 $\boxtimes$ 

(1) within three (3) months of the filing date of a national application other than a continued prosecution application under 37 C.F.R. 1.53(d), or within three (3) months of the date of entry of the national stage as set forth in 37 C.F.R. 1.491 in an

Information Disclosure Statement Serial No. 09/545,162 Page 2 of 2

		international application, or merits, or before the mailing continued examination under	before the mailing of the <b>first Office action</b> on the g of a <b>first Office action</b> after the filing of a request for er 37 C.F.R. 1.114; or
	(2)	after the period defined in ( of allowance under 37 C.F.	1) but before the mailing date of a <b>final action</b> or a <b>notice</b> R. 1.311, and
		the requisite Statement is be	elow, OR
		the requisite fee under 37 C.	F.R. 1.17(p), namely \$180.00, is included herein, or
	(3)	after the mailing date of a fit of the issue fee, AND	nal action or notice of allowance but before the payment
		the requisite Statement is be	low, AND
		the requisite petition fee und	ler 37 C.F.R. 1.17(p), namely \$180.00 is included herein.
			e patents and publications listed on the attached Form rein, be made of record in this application.
			Respectfully submitted,
Date: June Reg. No. 51	<u>5</u> , 20 ,752	003	Jewille Chart  Jewilfer E. Grant  Attorney for Applicant(s)  Testa, Hurwitz, & Thibeault, LLP
ГеІ. No.: (6 Fax No.: (6	•		High Street Tower 125 High Street Boston, Massachusetts 02110

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A PORMATION DISCLOSURE STATEMENT

ATTORNEY DOCKET NO.: EXT-026

APPLICANT(S): Lapidus et al.

SERIAL NO.: 09/545,162

FILING DATE: April 7, 2000

GROUP: 1634

EXAM.		DOCUMENT				SUB	FILING DATE IF
INIT.		NUMBER	DATE	NAME	CLASS	CLASS	APPROPRIATE
	Al	4,333,734	6/8/82	Fleisher			10/8/80
	A2	4,535,058	8/13/85	Weinberg et al.			10/1/82
	A3	4,683,195	7/28/87	Mullis et al.			2/7/86
	A4	4,786,718	11/22/88	Weinberg et al.		-	8/8/85
<del></del>	A5	4,857,300	8/15/89	Maksem			7/27/87
	A6	4,871,838	10/3/89	Bos et al.			7/23/85
	A7	4,981,783	1/1/91	Augenlicht			4/16/86
	A8	4,982,615	1/8/91	Sultan et al.			4/18/89
	A9	5,087,617	2/11/92	Smith			2/15/89
	A10	5,126,239	6/30/92	Livak et al.			3/14/90
-	A11	5,137,806	8/11/92	LeMaistre et al.			12/11/89
	A12	5,196,167	3/23/93	Guadagno et al.			5/9/91
	A13	5,248,671	9/28/93	Smith			12/9/91
· · · · · · · · · · · · · · · · · · ·	A14	5,272,057	12/21/93	Smulson et al.			12/21/93
	A15	5,302,509	4/12/94	Cheeseman		<b>5</b> 0000	2/27/91
	A16	5,330,892	7/19/94	Vogelstein et al.			3/13/91
	A17	5,348,855	9/20/94	Dattagupta et al.			10/4/91
	A18	5,352,775	10/4/94	Albertsen et al.			8/8/91
	A19	5,362,623	11/8/94	Vogelstein et al.			3/31/92
	A20	5,369,004	11/29/94	Polymeropoulos et al.			7/31/92
	A21	5,378,602	1/3/95	Polymeropoulos et al.			11/27/91
	A22	5,380,645	1/10/95	Vogelstein			3/16/89
	A23	5,380,647	1/10/95	Bahar			4/26/93
	A24	5,382,510	1/17/95	Levine et al.			7/10/92
	A25	5,409,586	4/25/95	Kamahori et al.			8/24/93

EXAMINER	DATE CONSIDERED

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EXAM. INIT.		DOCUMENT				SUB	FILING DATE IF
INII.		NUMBER	DATE	NAME	CLASS	CLASS	APPROPRIATE
	A26	5,458,761	10/17/95	Kamahori et al.			1/27/95
	A27	5,466,576	11/14/95	Schulz et al.			7/2/93
	A28	5,468,610	11/21/95	Polymeropoulos et al.			6/9/93
	A29	5,468,613	11/21/95	Erlich et al.			3/9/90
	A30	5,489,508	2/6/96	West et al.			3/24/93
	A31	5,492,808	2/20/96	de la Chapelle et al.			5/5/93
	A32	5,496,470	3/5/96	Lenhart			5/27/94
_	A33	5,508,164	4/16/96	Kausch et al.			10/29/93
_	A34	5,512,441	4/30/96	Ronal			11/15/94
	A35	5,514,547	5/7/96	Balazs et al.			2/4/94
	A36	5,527,676	6/18/96	Vogelstein et al.			3/22/93
- <del> </del>	A37	5,532,108	7/2/96	Vogelstein			4/14/94
	A38	5,580,729	12/3/96	Vogelstein			6/24/94
	A39	5,589,335	12/31/96	Kearney et al.			8/11/94
	A40	5,670,325	9/23/97	Lapidus et al.			8/14/96
***	A41	5,709,998	1/20/98	Kinzler et al.			12/15/93
	A42	5,710,028	1/20/98	Eyal et al.			10/4/94
	A43	5,741,650	4/21/98	Lapidus et al.			4/21/98
	A44	5,759,777	6/2/98	Kearney et al.			6/2/98
	A45	5,830,665	11/3/98	Shuber et al.			3/3/97
	A46	5,928,870	7/27/99	Lapidus et al.			6/16/97
	A47	3,413,464	11/26/68	Kamentsky			04/29/65
	A48	4,101,279	7/18/78	Aslam			4/6/77
	A49	4,309,782	1/12/82	Paulin			9/11/80
•	A50	4,358,535	11/9/82	Falkow et al.			12/8/90

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EXAM. INIT.		DOCUMENT				SUB	FILING DATE IF
INII.		NUMBER	DATE	NAME	CLASS	CLASS	APPROPRIATE
	A51	4,445,235	5/1/84	Slover et al.			9/13/82
	A52	4,578,358	3/25/86	Oksman et al.			5/3/83
	A53	4,683,202	7/28/87	Mullis			10/25/85
	A54	4,705,050	11/10/87	Markham			10/2/85
	A55	4,735,905	4/5/88	Parker			8/15/86
	A56	4,935,342	6/19/90	Seligson et al.			12/1/86
	A57	5,149,506	9/22/92	Skiba et al.			8/9/91
	A58	5,200,314	4/6/93	Urdea			3/23/90
	A59	5,331,973	7/26/94	Fiedler et al.		·	3/15/93
	A60	5,416,025	5/16/95	Krepinsky, et al.			8/31/94
	A61	5,463,782	11/7/95	Carlson et al.		-	11/21/94
	A62	5,482,834	1/9/96	Gillespie			1/19/93
	A63	5,506,105	4/9/96	Haydock			3/22/94
	A64	5,538,851	7/23/96	Fach et al.			12/22/93
	A65	5,559,014	9/24/96	Estes et al.			6/7/95
	A66	5,599,662	2/4/97	Respess			2/17/95
	A67	5,612,473	3/18/97	Wu et al.			1/16/96
	A68	5,635,352	6/03/97	Urdea et al.			4/26/95
	A69	5,641,628	6/24/97	Bianchi			11/14/94
	A70	5,645,995	7/8/97	Kieback			4/12/96
	A71	5,688,643	11/18/97	Oka et al.			2/27/95
	A72	5,846,710	12/8/98	Bajaj			8/6/93
	A73	5,856,104	1/5/99	Chee et al.			3/7/97
	A74	5,882,865	03/16/99	Vogelstein et al.			1/10/97
	A75	5,888,778	3/30/99	Shuber			6/16/97

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E PART		DOCUMENT				SUB	FILING DATE IF
INIT.		NUMBER	DATE	NAME	CLASS	CLASS	APPROPRIATE
	A76	5,910,407	6/8/99	Vogelstein et al.	1		8/26/94
	A77	5,916,744	6/29/99	Taylor			3/14/94
	A78	5,942,396	8/24/99	Shiff et al.			8/19/97
	A79	5,952,178	9/14/99	Lapidus et al.	1		4/13/98
	A80	5,976,800	11/2/99	Lau et al.	+	<del>                                     </del>	6/27/97
	A81	6,020,137	2/1/00	Lapidus et al.	+		11/23/98
	A82	6,037,465	3/14/00	Hillebrand et al.	†	<b></b>	12/16/96
	A83	6,100,029	8/8/00	Lapidus et al.	<del>                                      </del>	<del> </del>	12/4/97
	A84	6,143,529	11/7/00	Lapidus et al.	+		3/26/99
	A85	6,146,828	11/14/00	Lapidus	+		7/3/98
	A86	6,177,251B1	01/23/01	Vogelstein et al.	+		6/8/99
	A87	6,203,993 B1	3/20/01	Shuber et al.			4/4/00
	A88	6,214,187B1	4/10/01	Hammond et al.	+		6/18/99
	A89	6,214,558B1	04/10/01	Shuber et al.	+		7/27/00
	A90	6,238,927B1	5/29/01	Abrams et al.	<del>   </del>		10/4/99
	A91	6,251,660 B1	6/26/01	Muir et al.			11/25/98
	A92	6,268,136B1	7/31/01	Shuber et al.			11/23/98
	A93	6,280,947 B1	8/28/01	Shuber et al.	+		8/11/99
	A94	6,300,077 B1	10/9/01	Shuber et al.	<del>  </del>		4/4/00
	A95	6,303,304 B1	10/16/01	Shuber et al.			2/2/99
	A96	6,351,857 B2	3/5/02	Slaon, III et al.	<del>                                     </del>		3/13/01
	A97	6,406,857 B1	6/18/02	Shuber et al.			5/21/01
	A98	6,415,455 B1	7/9/02	Slaon, III et al.	-		12/17/01
	A99	6,428,964 B1	8/6/02	Shuber			3/15/01
	A100	6,475,738 B2	11/5/02	Shuber et al.		+	6/18/01

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EXAM. INIT.		DOCUMENT				SUB	FILING DATE IF
	<u></u>	NUMBER	DATE	NAME	CLASS	CLASS	APPROPRIATE
	A101	6,482,595 B2	11/19/02	Shuber et al.			8/27/01
	A102	2001/0018180A1	8/30/01	Shuber et al.			1/10/01
	A103	2002/0025525A1	2/28/02	Shuber			5/30/01
	A104	2002/0110810A1	8/15/02	Shuber			1/5/01
	A105	2002/0119469A1	8/29/02	Shuber et al.			10/5/01
	A106	2002/0119472A1	8/29/02	Lapidus et al.			10/15/01
-	A107	2002/0132251A1	9/19/02	Shuber			11/20/01
	A108	2002/0164631A1	11/7/02	Shuber et al.			3/25/02
	A109	6,150,100	11/21/00	Ruschoff et al.			3/25/98
	A110	6,448,002B1	9/10/02	Hillebrand et al.			8//26/97
	A111	6,084,091	7/4/00	Muller et al.			8/14/96
	A112	6,503,718 B2	1/7/03	Shuber et al.			1/10/01
	A113	6,551,777	4/22/03	Shuber et al.		-	1/24/00
	A114	6,498,012	12/24/02	Laken	<del></del>		6/18/01
	A115	2003/0087258A1	5/8/03	Shuber			4/11/02
	A116	2003/0044780A1	3/6/03	Lapidus et al.			11/23/99
	A117	2003/0049659A1	3/13/03	Lapidus et al.			5/29/02

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EXAM. INIT.		DOCUMENT NUMBER	DATE	COUNTRY CODE	CLASS	SUB CLASS	FILING DATE	ABSTRACT ONLY	ENGLISH LANG Y/N
	B1	0 284 362 A2	9/28/88	EP			3/23/88		Y
	B2	0 337 498 A2	10/18/89	EP			4/17/89		Y
	В3	WO 90/09455	8/23/90	PCT			2/13/90		Y
	B4	0 390 323 A2	10/3/90	EP			2/20/90		Y
	B5	0 390 323 A3	10/3/90	EP			2/20/90		Y
	В6	0 407 789 A1	1/16/91	EP			6/22/90		Y
	В7	0 407 789 B1	1/16/91	EP	•		6/22/90		Y
	B8	WO 92/13103	8/6/92	PCT			1/16/92		Y
	В9	WO 92/16657	10/1/92	PCT			3/12/92		Y
	B10	WO 93/18186	9/16/93	PCT			3/1/93		Y
	B11	WO 93/20233	10/14/93	PCT			3/22/93		Y
	B12	WO 94/01447	1/20/94	PCT			7/1/93		Y
	B13	WO 94/09161	4/28/94	PCT			10/20/93		Y
	B14	WO 94/10575	5/11/94	PCT			10/29/93		Y
	B15	WO 94/11383	5/26/94	PCT			11/8/93		Y
	B16	0 608 004 A2	7/27/94	EP			8/11/87		Y
	B17	A-11325/95	10/5/94	AU					Y
	B18	0 259 031 B1	11/9/94	EP			8/11/87		Y
	B19	WO 95/07361	3/16/95	PCT			9/9/94	Abstract in English	N
	B20	WO 95/09928	4/13/95	PCT			9/26/94		Y
	B21	WO 95/09929	4/13/95	PCT			9/26/94		Y
	B22	0 648 845 A2	4/19/95	EP			7/2/94		Y
	B23	WO 95/13397	5/18/95	PCT			11/10/94		Y
	B24	WO 95/15400	6/8/95	PCT			12/5/94		Y

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## FOREIGN PATENT DOCUMENTS

Phone!	<u> </u>	DOCUMENT		COUNTRY		GUE	T	T	Т
INIT.		NUMBER	DATE	COUNTRY	CLASS	SUB CLASS	FILING DATE	ABSTRACT ONLY	ENGLISH LANG Y/N
	B25	WO 95/16792	6/22/95	PCT			12/13/94	Abstract in English	N
	B26	WO 95/18818	7/13/95	PCT			1/3/95		Y
	B27	WO 95/19448	7/20/95	PCT			1/13/95		Y
	B28	0 664 339 A1	7/26/95	EP			7/7/94		Y
	B29	WO 95/25813	9/28/95	PCT		-	3/17/95		Y
	B30	WO 95/31728	11/23/95	PCT			5/15/95		Y
	B31	WO 96/01907	1/25/96	PCT			7/10/95		Y
	B32	WO 96/06951	3/7/96	PCT			8/31/95		Y
	B33	WO 96/08514	3/21/96	PCT			9/12/95		Y
	B34	WO 96/12821	5/2/96	PCT			12/19/95		Y
	B35	WO 96/13611	5/9/96	PCT			10/27/95		Υ
	B36	WO 96/30545	10/3/96	PCT			2/14/96		Y
	B37	WO 97/09449	3/13/97	PCT			9/2/96		Y
	B38	WO 97/09600	3/13/97	PCT			9/5/96		Y
	B39	WO 97/23651	7/3/97	PCT			12/20/96		Y
	B40	WO 97/25442	7/17/97	PCT			1/9/97		Y
	B41	WO 98/38338	9/3/98	РСТ			2/27/98		Y
	B42	WO 98/58081	12/23/98	PCT			6/4/98		Y
	B43	0 270 017A2	6/8/88	EP			11/27/87		Y
	B44	0 270 017A3	6/8/88	EP			11/27/87		Y
	B45	0 284 362 A3	9/28/88	EP			3/23/88		Y
	B46	0 391 565 B1	10/10/90	EP			3/19/90		Y
	B47	195 30 132C2	2/20/97	DE			8/16/95	A111 is English counterpart	N

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ATTORNEY DOCKET NO.: EXT-026

APPLICANT(S): Lapidus et al.

SERIAL NO.: 09/545,162

FILING DATE: April 7, 2000 GROUP: 1634

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	B48	197 12 332A1	10/1/98	DE			3/25/97	A109 is English counterpart	N
	B49	197 36 691A1	2/25/99	DE			8/22/97	B111 has English abstract	N
	B50	2,327,497A	1/27/99	GB			7/15/98		Y
	B51	WO 93/20235	10/14/93	PCT			3/31/93		Y
	B52	WO 94/00603	1/6/94	PCT			6/28/93		Y
	B53	WO 94/01447	1/20/94	PCT			7/1/93		Y
	B54	WO 95/00669	1/5/95	PCT			6/22/94		Y
	B55	WO 95/12606	5/11/95	PCT			11/5/93		Y
	B56	WO 96/23895A	8/8/96	PCT			1/29/96		Y
	B57	WO 96/29430A	9/26/96	PCT			3/13/96		Y
	B58	WO 97/07239	2/27/97	PCT			8/14/96	A111 is English counterpart	N
	B59	WO 97/19191A	5/29/97	PCT			11/15/96		Y
	B60	WO 97/28450	8/7/97	PCT			12/20/96		Y
	B61	WO 98/08971	3/5/98	PCT			8/26/97	A110 is English counterpart	N
	B62	WO 98/39478	9/11/98	PCT			3/2/98	·	Y
	B63	WO 98/58084	12/23/98	PCT			6/16/98		Y
	B64	WO 99/07894	2/18/99	PCT			8/5/98		Y
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	B69	WO 99/45374	9/10/99	PCT			3/3/99		Y
	B70	WO 99/53316	10/21/99	PCT			4/13/99		Y
	B71	WO 99/55912	11/4/99	PCT			4/23/99		Y
	B72	WO 99/66077	12/23/99	PCT			6/16/99		Y
	B73	WO 99/66078	12/23/99	PCT			6/18/99		Y
	B74	WO 99/66079	12/23/99	PCT			6/18/99		Y
	B75	WO 00/09751	2/24/00	PCT			8/10/99		Y
	B76	WO 00/11215	3/2/00	PCT			8/10/99		Y
	B77	WO 00/31298	6/2/00	PCT			11/17/99		Y
	B78	WO 00/31303	6/2/00	PCT			11/22/99		Y
	B79	WO 00/31305	6/2/00	PCT			11/23/99		Y
	B80	WO 00/32820	6/8/00	PCT			11/23/99		Y
	B81	WO 00/50640	8/31/00	PCT			1/24/00		Y
	B82	WO 00/50870	8/31/00	PCT			2/25/00		Y
	B83	WO 00/58514A3	10/5/00	PCT			3/24/00		Y
	B84	WO 00/60118	10/12/00	PCT			3/31/00		Y
	B85	WO 00/61808A3	10/19/00	PCT			4/7/00		Y
	B86	WO 00/66005	11/9/00	PCT			4/26/00		Y
	B87	WO 00/70096	11/23/00	PCT			5/18/00		Y
	B88	WO 00/70096A3	11/23/00	PCT			5/18/00		Y
	B89	WO 01/18252A2	3/15/01	РСТ			9/8/00		Y
	B90	WO 01/42502A2	6/14/01	PCT			9/8/00		Y
	B91	WO 01/42503A2	6/14/01	PCT			11/28/00		Y
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FILING DATE: April 7, 2000

GROUP: 1634

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# INFORMATION DISCLOSURE STATEMENT

ATTORNEY DOCKET NO.: EXT-026

APPLICANT(S): Lapidus et al.

SERIAL NO.: 09/545,162

FILING DATE: April 7, 2000 GROUP: 1634

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